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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Theodoric Mattes at 240-627-3827, or *theodoric.mattes@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Lymphatic filariasis biomarkers for detection and surveillance

Description of Technology:

Lymphatic filariasis (elephantiasis; LF) is a neglected tropical disease that affects over 120 million people throughout the tropics and sub-tropics of Asia, Africa, the Western Pacific, and parts of the Caribbean and South America. LF results from infection with the filarial parasites *Wuchereria bancrofti* or *Brugia malayi.* Current methods of confirming active infection by *W. bancrofti* or *B. malayi* include microscopy and immunoassays using serum/plasma extracted from the patient. However, the sensitivity of microscopy detection varies among patients, and immunoassays show cross-reactivity with antibodies directed towards other parasites, such as *Onchocerca volvulus* or *Loa loa* whose geographic distribution can overlap with the LF-causing filarial parasites.

This new technology addresses the limitations of cross-reactivity through the detection of a single antigen, Wb5B, selected due to a lack of homologs in other filarial parasites that infect humans. Preliminary data indicates that Wb5B is immunogenic, highly specific (>99%), and accurate (>90%) for the detection of *W. bancrofti* infection in sera from humans and other mammalian sources. The antigen can be isolated in soluble form for integration in a variety of diagnostic assay formats.

The subject technology, including the antigen sequence as well as plasmids enabling bacterial, insect, and mammalian cell expression, is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

There may be the potential to combine this technology with another NIAID-developed biomarker technology (Wb123, available for licensing; see HHS Ref. No. E-281-2010-0, "Diagnostic Assays and Methods of Use for Detection of Filarial Infection") for the development of a multiplex assay for detection of active *W. bancrofti* infection for diagnostic or surveillance purposes.

Potential Commercial Applications:

- Diagnostics for *W. bancrofti* infection

- Surveillance for *W. bancrofti* prevalence

Competitive Advantages:

- Increased specificity compared to available diagnostics
- Differentiation from other parasites with similar geographic footprints

Development Stage: Pre-Clinical

Inventors: Thomas B. Nutman, Sasisekhar Bennuru, both of NIAID

Intellectual Property: U.S. Provisional Patent Application Serial No. 63/347,794, filed June 1, 2022

Related Inventions: Diagnostic Assays and Methods of Use for Detection of Filarial Infection (HHS Reference No. E-281-2010-0)

Licensing Contact: To license this technology, please contact Theodoric Mattes at 240-627-3827, or *theodoric.mattes@nih.gov.*, and reference E-093-2022-0.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Theodoric Mattes at 240-627-3827, or *theodoric.mattes@nih.gov.*

Date: July 14, 2022.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2022-15910 Filed: 7/25/2022 8:45 am; Publication Date: 7/26/2022]